UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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RACHEL EPSTEIN,
MAUREEN BRINKMAN,
DEBORAH O'CONNELL

Plaintiffs,

CASE NUMBER: CV-19-6060

COMPLAINT
AND DEMAND
FOR JURY TRIAL

-against-

ELI LILLY AND COMPANY; E.R. SQUIBB & SONS, INC. n/k/a BRISTOL-MYERS SQUIBB

Defendants.
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This is an action brought to recover damages due to in utero exposure of Diethylstilbestrol ("DES"). Plaintiffs RACHEL EPSTEIN, MAUREEN BRINKMAN, and DEBORAH O'CONNELL by their attorney SYBIL SHAINWALD, Esq., upon information and belief, at all times hereinafter mentioned, allege as follows:

JURISDICTION

1. This Court has jurisdiction pursuant to 28 United States Code Section 1332, in that Plaintiffs are citizens of states which are different from the States where Defendants are incorporated and have their principal places of business. The amount in controversy exceeds SEVENTY-FIVE THOUSAND DOLLARS ($75,000.00) as to each Plaintiff.

PARTY PLAINTIFF

2. Plaintiff RACHEL EPSTEIN was born on July 24, 1954 and at all times relevant herein was a resident of the State of California.

3. Plaintiff MAUREEN BRINKMAN was born on August 17, 1959 and at all times relevant herein was a resident of the State of Wisconsin.

4. Plaintiff DEBORAH O'CONNELL was born on February 12, 1956 and at all times relevant herein was a resident of the State of Hawaii.

PARTY DEFENDANTS

5. Eli Lilly And Company is a corporation incorporated under the laws of the State of Indiana with its principal place of business in Indiana.

6. E.R. Squibb & Sons, Inc., n/k/a Bristol-Myers Squibb is a corporation incorporated under the laws of the State of Delaware with its principal place of business in New York.

FACTUAL BACKGROUND

7. At all relevant times, Defendants were in the business of and did create, design, manufacture, test, formulate, advertise, market, promote, sell, and/or distribute the drug DES.

8. During the period in and about 1940 and prior and subsequent thereto, Defendants assisted each other to prepare the drug DES, which thereupon became a generic drug manufactured by them and by other drug companies. Defendants also assisted each other to exploit, market and secur permission from the Food and Drug Administration ("FDA") to publicly sell DES for ingestion by women. Defendants knew and were aware, or should have known, that the drug had not been tested and lacked warnings. Nevertheless, these Defendants endeavored to obtain FDA approval of DES and bring it to market, thereby enabling others and themselves to market a drug resulting in harm to the offspring of users.

9. The Defendants made certain claims and representations that were contained in their Supplemental New Drug Application, some of which were that the use of DES in the prevention of miscarriages and accidents in pregnancy was both safe and efficacious.

10. The Defendants made certain claims that were distributed and circulated to the medical profession and to the general public through advertising, literature, detailmen, brochures and other materials stating that DES was a safe and efficacious drug for the treatment of accidents in pregnancy.

11. At the time, these Defendants knew or should have known that DES had the potential to become harmful to the offspring of users and knew or should have known that the drug was ineffective for the purpose for which it was marketed and sold.

12. Upon information and belief, these Defendants secured FDA approval; brought DES to the market where it was produced by these Defendants and/or other drug companies with the same content and same potential for harm; and distributed and marketed DES to the public so as to induce its use in the manner in which it was used by Plaintiff's mother.

13. Upon information and belief, these Defendants misrepresented the risks inherent in the use of DES in their applications to the FDA and to other governmental persons and/or agencies.

14. Defendants knew, or should have known, of the above-mentioned risks based upon the state of knowledge as it existed at that time and upon generally accepted medical and research standards and principles.

15. The Defendants, their agents, servants and/or employees, manufactured, produced, promoted, formulated, created or designed DES without testing it for use in

pregnancy, without making proper and sufficient tests to determine the dangers and contra-indications thereof, and without warning the public and the medical profession of the dangers and contra-indications and side effects inherent in the drug. The Defendants also negligently recommended the use of DES without sufficient knowledge as to its dangerous propensities; represented that the drug was safe for use for its intended purpose, when, in fact, it was unsafe; and failed to conduct sufficient testing programs to determine whether or not the drug was safe for use. Defendants knew or should have known that said drug was unsafe and unfit for use by reason of the dangerous effects, contra-indications and dangers to a fetus during the pregnancy.

16. Defendants, their agents, servants and/or employees, improperly obtained the approval of the FDA to market the drug by misrepresenting the risks of the drug to the FDA; knew that it was a substance, which crossed the placenta and therefore could cause injury to a fetus in utero; and were otherwise reckless and negligent.

17. Defendants, by their agents, servants and/or employees were careless and negligent in the manufacturing, selling, distribution, merchandising, advertising, promotion, compounding, packaging, fabrication, analyzing, marketing, and recommendation of the drug DES without making proper and sufficient tests to determine the dangers thereof.

18. In this action, Plaintiffs claim that they were exposed to DES in utero and that their mothers ingested DES, which was marketed by Defendants.

19. By reason of the foregoing, those exposed to DES have developed, or are at extremely high risk for experiencing certain cancers, infertility, ectopic pregnancies, as well as other serious injuries; and Plaintiffs herein has sustained severe, serious, permanent and personal injuries; will require extensive hospitalizations, medical care, surgeries, and lifelong attention; will be incapacitated from her normal functioning and will be unable to pursue normal means of

livelihood; will be precluded from having a normal life, physically, intellectually, vocationally, emotionally, or psychologically; and Plaintiffs have been otherwise seriously damaged.

20. Whether or not Plaintiffs prove which particular manufacturer produced the drug ingested by Plaintiffs' mothers, Defendants will be liable to them, based on theories of market share liability, because they marketed the drug for pregnancy use.

FIRST CLAIM FOR RELIEF
(Strict Products Liability)

21. Plaintiffs repeat, reiterate and reallege each and every allegation contained in the paragraphs numbers "1" through "20", inclusive, with the same force and effect as if hereinafter set forth at length.

22. At all times herein mentioned, the Defendants, manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, sold, purchased, prescribed, and administered the aforesaid DES as hereinabove described and prior to the time that Plaintiffs or Plaintiffs' mothers, and thereby Plaintiffs, used said product.

23. The drug product, more particularly known as DES, was expected to and did reach the consumers and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, and marketed by the Defendants.

24. At all times, the said drug product DES, was in an unsafe, defective, and inherently dangerous condition, which was dangerous to users, the general public and, in particular, the Plaintiffs herein.

25. Defendants, while regularly engaged in the business activities aforementioned, did design, develop, manufacture, produce, sell, market and/or distribute DES, which was ingested by Plaintiffs' mothers.

26. At all times herein mentioned, the said drug product DES was in a defective and unsafe condition and Defendants, individually, jointly, and severally, knew or had reason to know that the product was defective, unsafe, and inherently dangerous especially when used as a miscarriage preventative.

27. At the time of the occurrence and ingestion by Plaintiffs' mothers, DES was being used for the purposes and a manner normally intended.

28. Neither Plaintiffs nor their mothers could, by the exercise of reasonable care, have discovered the defects herein mentioned and/or perceived their danger.

29. As a direct and proximate result of the defective condition of DES manufactured and supplied by Defendants, Plaintiffs were caused to sustain severe and grievous personal injuries, as described herein.

30. By reason of the foregoing, the Defendants have become strictly liable in tort to the Plaintiffs for the marketing of a defective product, regardless of whether they marketed the particular pill taken by Plaintiffs' mothers.

31. By reason of the foregoing, Plaintiffs have been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

SECOND CLAIM FOR RELIEF

(Negligence)

32. Plaintiffs repeat, reiterate and reallege each and every allegation contained in the paragraphs numbers "1" through "31", inclusive, with the same force and effect as if more fully set forth herein.

33. The negligence of the Defendants, their agents, servants, and/or employees, included but was not limited to the following acts or omissions:

(a) manufacturing, producing, promoting, formulating, creating, and designing DES without testing it for use in pregnancy;

(b) selling DES without making proper and sufficient tests to determine the dangers and contra-indications thereof;

(c) negligently failing to adequately and correctly warn the public and the medical profession of the dangers and contra-indications and side effects inherent in the aforesaid drug and failing to provide adequate instructions regarding safety precautions to be observed by users and persons who would reasonably and foreseeably come into contact with DES;

(d) negligently advertising and recommending the use of the aforesaid drug without sufficient knowledge as to its dangerous propensities;

(e) negligently representing that the said drug was safe for use for its intended purpose, when, in fact, it was unsafe;

(f) not conducting testing to determine whether or not the drug was safe for use; in that Defendants herein knew or should have known that the drug was unsafe and unfit for use by reason of the dangerous side

effects, contra-indications and dangers to a fetus during the pregnancy of its mother; and

(g) improperly obtaining the approval of the FDA to market the drug by misrepresenting the risks of the drug to the FDA; in knowing that it was a substance that crossed the placental and therefore could cause injury to a fetus.

34. As a direct and proximate result of the aforementioned negligence on the part of the Defendants, Plaintiffs were caused to sustain severe and grievous personal injuries, as set forth herein.

35. By reason of Defendants' actions as aforementioned, Defendants are liable to Plaintiffs regardless of whether or not they manufactured the particular DES drug ingested by Plaintiffs' mothers.

36. By reason of the foregoing, the Plaintiffs have been damaged as against Defendants in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

THIRD CLAIM FOR RELIEF
(Breach of Express Warranty)

37. Plaintiffs repeat, reiterate and reallege each and every allegation contained in the paragraphs numbers "1" through "36", inclusive, with the same force and effect as if more fully set forth herein at length.

38. Defendants, each of them, expressly represented to the users and their physicians that DES was safe and fit for use for the purposes intended, that it was of merchantable quality, and that it did not produce any side effects dangerous to life, and that it was adequately tested and fit for its intended use.

39. Members of the medical community relied upon the representations and warranties of the Defendants for use and ingestion of DES in prescribing, recommending, and/or dispensing said drug.

40. Defendants knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that DES was not safe and fit for the use intended, and, in fact, produces serious injuries to the user and the offspring of the user.

41. As a result of the aforementioned breach of warranties by Defendants, Plaintiffs were caused to sustain severe and grievous personal injuries, as set forth herein.

42. By reason of Defendants' actions as aforementioned, Defendants are liable to Plaintiffs regardless of whether or not they manufactured the particular DES drug ingested by Plaintiffs' mothers.

43. By reason of the foregoing, Plaintiffs have been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

FOURTH CLAIM FOR RELIEF
(Breach of Implied Warranty)

44. Plaintiffs repeat, reiterate and reallege each and every allegation contained in the paragraphs numbers "1" through "43", inclusive, with the same force and effect as if more fully set forth herein.

45. At all times herein mentioned, the Defendants, and each of them, manufactured, compounded, portrayed, distributed, recommended, merchandised, advertised, promoted, sold, purchased, prescribed, and administered DES as described above and prior to the time that Plaintiffs' mothers, and thereby Plaintiffs, used said product.

46. The Defendants, and each of them, impliedly represented and warranted to the users and their physicians that the aforementioned drug product, more particularly known as DES, was safe and of merchantable quality and fit for the ordinary purpose for which said product was to be used.

47. The representations and warranties aforementioned were false, misleading, and inaccurate in that DES was unsafe, unreasonably dangerous, improper, not of merchantable quality, and defective.

48. DES products were injected into the stream of commerce by the Defendants in a defective, unsafe, and inherently dangerous condition and the products and materials were expected to and did reach users, handlers, and persons coming into contact with said products without substantial change in the condition in which they were sold.

49. As a result of the aforementioned breach of warranties by Defendants, Plaintiffs were caused to sustain severe and grievous personal injuries, as set forth herein.

50. By reason of Defendants' actions as aforementioned, Defendants are liable to Plaintiffs regardless of whether or not they manufactured the particular DES drug ingested by Plaintiffs' mothers.

51. By reason of the foregoing, Plaintiffs have been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

FIFTH CLAIM FOR RELIEF
(Fraudulent Misrepresentation)

52. Plaintiffs repeat, reiterate and reallege each and every allegation contained in the paragraphs numbers "1" through "51", inclusive, with the same force and effect as if more fully set forth herein at length.

53. The Defendants falsely and fraudulently represented to the medical community and to the public in general that DES was a drug that had been tested and found to be safe and effective for the prevention of miscarriages and other pregnancy related uses. The representations made by Defendants were, in fact, false.

54. When representations were made by Defendants, they individually, jointly, and severally, knew those representations to be false, willfully, wantonly and recklessly disregarded whether the representations were true, and these representations were made by Defendants with the intent of defrauding and deceiving the public in general, and the medical community in particular, to prescribe, dispense and purchase DES for the prevention of miscarriages, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of the Plaintiffs.

55. At the time the aforesaid representations were made by the Defendants, and, at the time that Plaintiffs' mothers ingested DES, Plaintiffs' mothers and Plaintiffs were ignorant of the falsity of said representations, and reasonably believed them to be true. In reliance upon the representations, Plaintiffs' mothers were induced to and did take DES during their pregnancies with their daughters, the Plaintiffs.

56. As a result of the fraudulent misrepresentations of the Defendants set forth hereinabove, Defendants knew and were aware or should have known that the drug had been insufficiently tested, that it had not been tested or sufficiently tested on humans, or lacked adequate warnings, and these Defendants cooperated with others to obtain FDA approval of the drug and otherwise assisted other persons and drug companies to bring DES to market a drug involving harmful results to users and the offspring of users, thereby breaching their duty to such users and aiding and assisting other persons and drug companies marketing DES to do the same.

57. At this time, these Defendants and other persons and drug companies with whom they were cooperating and exchanging mutual assistance in order to bring DES to the market and secure approval thereof, knew or should have known that DES, its components and in combination, had a potential to, could, and would cause severe and grievous injury to the user and to the offspring of the users of said product and that the drug was ineffective for the purpose for which it was marketed and sold and was inherently dangerous.

58. These Defendants and other persons and drug companies, as a result of the mutual aid of each to the other and in combination, secured FDA approval, brought DES to the market where it was produced by these Defendants and other drug companies with the same content and the same potential for harm, and these Defendants and the other persons and drug companies conferred and assisted in promoting and advertising, and said Defendants acted fraudulently, wantonly and maliciously to the detriment of the Plaintiffs.

59. As a result of Defendants' fraudulent and deceitful conduct and representations, Plaintiffs were caused to sustain severe and grievous personal injuries, as set forth herein.

60. By reason of Defendants' actions as aforementioned, Defendants are liable to Plaintiffs regardless of whether or not they manufactured the particular DES drug ingested by Plaintiffs' mothers.

61. By reason of the foregoing, Plaintiffs have been damaged as against each defendant in the sum of TEN MILLION DOLLARS ($10,000,000.00) in compensatory damages and TEN MILLION DOLLARS ($10,000,000.00) in punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs RACHEL EPSTEIN, MAUREEN BRINKMAN, DEBORAH O'CONNELL demands judgment against each Defendant on each cause of action with interest together and with the costs and disbursements of this action.

DEMAND FOR JURY TRIAL

Plaintiffs hereby demands trial by jury as to all issues.

Dated: New York, New York
October 28, 2019

LAW OFFICE OF SYBIL SHAINWALD

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